IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON,
Plaintiff,

v. CIVIL ACTION NO. 3:17-01362

AMERISOURCEBERGEN
DRUG CORPORATION, et al.,
Defendants.

CABELL COUNTY COMMISSION,
Plaintiff,

v. CIVIL ACTION NO. 3:17-01665

AMERISOURCEBERGEN
DRUG CORPORATION, et al.,
Defendants.

AMERISOURCEBERGEN DRUG CORPORATION'S MEMORANDUM IN SUPPORT OF MOTION FOR JUDGMENT UNDER RULE 52(c) BASED ON PLAINTIFFS' FAILURE TO PROVE CULPABLE CONDUCT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Regulations

Other Authorities

PRELIMINARY STATEMENT

Because of Plaintiffs' complete failure of proof against AmerisourceBergen Drug Corporation (ABDC), ABDC respectfully seeks entry of judgment pursuant to Rule 52(c).

At the outset of the case, Plaintiffs promised to prove that "too many pills" were shipped into Cabell County and the City of Huntington as a result of systemic failures on the part of ABDC's diversion control program. None of this was proven. Plaintiffs were undone by the testimony of their own witnesses, none of whom even testified that too many prescription opioids had been shipped to Cabell and Huntington, let alone that ABDC should not have shipped any of them. Of great significance, Plaintiffs offered no evidence at all to address the core fact that every prescription opioid ABDC shipped went to a licensed pharmacy or hospital customer, who may dispense opioids only in response to a legitimate prescription written by a licensed physician. Nor did Plaintiffs offer any evidence whatsoever that ABDC had any visibility into the medical judgments underlying those prescriptions (which it does not) or that ABDC could override the prescribing physician's medical judgment—indeed, the evidence showed that ABDC cannot and should not. Plaintiffs' own evidence also established (1) that the change in the standard of care for treatment of pain during the relevant years had an effect on prescribing patterns, and (2) that Drug Enforcement Administration (DEA) had embraced that change, having steadily raised opioid production quotas during these same years.

Plaintiffs' liability theory also is based on their assertion that there were systemic failures in Defendants' diversion control programs, including their suspicious order monitoring programs. But there is no proof of that either. To the contrary, as for ABDC's conduct, including the design and operation of its suspicious order monitoring program, the evidence was uniformly positive for ABDC—and was fortified by the extensive testimony under cross examination of the four ABDC

witnesses Plaintiffs chose to call in their affirmative case. The facts that emerged were these: ABDC's regulator, DEA, formally approved ABDC's 1998 program in writing after working with ABDC to build it; DEA tacitly endorsed the next iteration of ABDC's program in 2007; and DEA consistently held out ABDC's program to the industry as a model to be emulated.

The evidence also is uncontroverted that, with the exception of a brief shutdown of ABDC's Orlando, Florida facility 14 years ago—which related exclusively to four internet pharmacies in Florida that had no connection at all to West Virginia—DEA has never brought an enforcement action against ABDC. And while ABDC resolved the brief Orlando shutdown through an agreement with DEA, ABDC did not then admit, and has never admitted, to any wrongdoing and has never paid any fine to DEA.

What was most remarkable about Plaintiffs' case was the absence of any testimony from their own witnesses, including experts, to support their position. On the issue of distribution volume, the key facts were these:

- Not a single witness testified that ABDC shipped too many prescription opioids.
- Not a single witness testified as to the "right" amount of prescription opioids that ABDC should have shipped to its customers in Cabell and Huntington.
- Not a single witness testified that the prescription opioids ABDC shipped to its licensed customers were used to fill anything other than legitimate prescriptions written by licensed doctors.
- Plaintiffs' "volume" expert, Craig McCann, admitted that he could not say whether the distribution volumes to which he testified reflected oversupply or undersupply. Nor could anyone else.

What Plaintiffs' witnesses ***did*** establish in their testimony about volumes was equally telling. Both Dr. McCann and Lacey Keller, two experts who separately compared Defendants' per capita distribution to physicians' per capita prescribing, demonstrated—practically down to the pill—that distribution and prescribing went hand in hand, and rose and fell in unison. And witness after witness affirmed that the change in the standard of care—nationally, in West Virginia,

and locally—influenced physicians to prescribe more opioids. Yet no witness even suggested, much less offered credible evidence, that ABDC had anything to do with the change in the standard of care or the increase in doctors writing opioid prescriptions.

The absence of any testimony or evidence of wrongful or "unreasonable" conduct by ABDC was equally pronounced. James Rafalski, a former Detroit police officer and then DEA investigator, was supposed to be Plaintiffs' featured witness on conduct. His testimony was a bust. He did not say a word about ABDC's conduct, and hardly mentioned the company at all. He proffered six different models, which yielded six different outcomes, supposedly to quantify the number of orders Defendants shipped that should have been identified as "suspicious." This turned out to be an entirely theoretical exercise with no factual underpinnings. Asked to identify which of the six models he thought was best, Mr. Rafalski—brazenly, but perhaps not surprisingly—chose the model that concluded that 90% of the orders placed by Defendants' customers were suspicious and should not have been shipped. This would be an absurd result that would have deprived untold numbers of people of Federal Drug Administration-approved medicines that had been prescribed to them by their doctor. This is hardly reliable expert testimony—it should be excluded (as this Court still may do), and it cannot support a conclusion that Plaintiffs have made out their case.

Joseph Rannazzisi, who was in charge of Diversion Control for DEA from 2005 to 2015, was supposed to be Plaintiffs' other main witness on "conduct." Mr. Rannazzisi's testimony about ABDC was sparse, and what little he did say was either neutral or positive. In a pivotal moment during his testimony, Plaintiffs tried—and failed—to elicit something negative about ABDC from Mr. Rannazzisi:

> Q. Mr. Rannazzisi, did DEA bring additional actions against AmerisourceBergen (after 2007 Orlando action) during your tenure as Deputy Assistant Administrator?

> A. I don't recall any additional actions against AmerisourceBergen.
>
> Q. And was the fact that DEA, to your knowledge, did not initiate an enforcement action against AmerisourceBergen a sign that, that you had found, or that DEA had found AmerisourceBergen's compliance with the Controlled Substances Act?
>
> A. No. The fact that there was no enforcement action doesn't mean they were compliant, doesn't mean they weren't compliant. We just didn't have – during our, our investigations, they did not come up.[1]

In other words, according to Mr. Rannazzisi, who was in charge of Diversion Control and repeatedly emphasized his own knowledge about distributors during his tenure, ABDC has not even "come up" since 2007—14 years ago.

On the issue of conduct, it must be emphasized that Plaintiffs offered no specific testimony that ABDC failed to report suspicious orders or that they should have reported more. To the contrary, the evidence affirmatively showed that ABDC ***did*** report suspicious orders as required by the Controlled Substances Act—and reported them for customers in Cabell and Huntington. It also uncontroverted that ABDC's post-2007 programs did ***not*** ship orders identified as suspicious. And there is no evidence that a single prescription opioid ABDC shipped into Cabell or Huntington was diverted—not one.

A fair review of the evidence Plaintiffs' have proffered in this trial can yield only one conclusion: They did not prove their case against ABDC. There is simply no evidence of unreasonable or improper conduct. In fact, on this record, which is set forth in detail below, there is a trove of evidence to the contrary, through the testimony of Chris Zimmerman (Senior Vice President – Corporate Security and Regulatory Affairs), Steve Mays (Vice President – Regulatory Affairs), David May (Vice President – Corporate Security and Diversion Control) and Mike Perry (ABDC's sales representative in Cabell/Huntington). The testimony of these four witnesses

[1] 6/8 Tr. at 72:6-19 (Rannazzisi).

establishes that ABDC complied with the law and acted reasonably during the entire time period at issue in this case. A directed verdict would be warranted here even in the absence of that testimony because of the Plaintiffs' utter lack of proof against ABDC. But such testimony provides first-hand knowledge, unfiltered through experts, of what the facts on the ground really were. That evidence is uncontroverted and the facts compel judgment in favor of ABDC.

LEGAL STANDARDS

A. Rule 52(c) Standard Of Review

Under Rule 52(c), once "a party has been fully heard on an issue," the court sitting as fact finder in a bench trial may issue a "judgment on partial findings" when it "finds against the party on that issue." Fed. R. Civ. P. 52(c); *see also, e.g.*, *Carter v. Ball*, 33 F.3d 450, 457 (4th Cir. 1994) ("A district court sitting without a jury may enter judgment as a matter of law against a party on any claim once the party has had a full opportunity to present evidence on that claim."); *First Virginia Banks, Inc. v. BP Expl. & Oil Inc.*, 206 F.3d 404, 407 (4th Cir. 2000) (Rule 52(c) "authorizes the court to enter judgment at any time that it can appropriately make a dispositive finding of fact on the evidence.")(citing Fed. R. Civ. P. 52 advisory committee's note (1991 Amendment)). The requirement "that a party be 'fully heard' does not mean that a party must be allowed to introduce every shred of evidence that a party wishes, without regard to the probative value of that evidence." *DLJ Mortg. Cap., Inc. v. Sheridan*, 975 F.3d 358, 366 (3d Cir. 2020) (citing *EBC, Inc. v. Clark Bldg. Systems, Inc.*, 618 F.3d 253, 272 n.21 (3d Cir. 2010)).

"In considering whether to grant judgment under Rule 52(c), the district court applies the same standard of proof and weighs the evidence as it would at the conclusion of the trial." *EBC, Inc.*, 618 F.3d at 272. Thus, unlike in other contexts, such as ruling on a summary judgment motion or a directed verdict motion in a jury trial, "the court does not view the evidence through a particular lens or draw inferences favorable to either party." *Id.* Instead, the "court's task is to

weigh the evidence, resolve any conflicts in it, and decide for itself where the preponderance of the evidence lies." Wright & Miller, Federal Practice & Procedure § 2573.1 (footnotes omitted); *see also Pinkston v. Madry*, 440 F.3d 879, 890 (7th Cir. 2006) ("[A] trial court ruling on a motion for judgment on partial findings under Rule 52(c) is acting in the capacity of a finder of fact, weighing evidence and assessing the credibility of the witnesses."); *M & M Poultry, Inc. v. Pilgrim's Pride Corp.*, 281 F. Supp. 3d 610, 620 (N.D. W. Va. 2017) ("Rule 52(c) expressly authorizes district judges to resolve disputed issues of fact.") (citing Fed. R. Civ. P. 52(c)).

B. Public Nuisance Culpable Conduct Standard

While the parties have offered differing views on the legal standard governing public nuisance claims, there is no debate that tort liability cannot be imposed unless the plaintiff proves the defendant did something wrong—that is, that the defendant engaged in culpable conduct or, as Plaintiffs' counsel characterized it during opening argument, "actionable conduct."[2]

Defendants may not be held liable merely for the lawful operation of their pharmaceutical distribution business, but only for ***wrongful*** conduct. *See Sharon Steel Corp. v. City of Fairmont*, 334 S.E.2d 616, 620 (1985) ("A public nuisance is an act or conduction that ***unlawfully*** operates to hurt or inconvenience and indefinite number of persons.") (emphasis added); ECF No. 1248 at 14 ("the relevant conduct" in this lawsuit is "not the lawful business of pharmaceutical drug distribution"). As for what is required to establish the wrongful conduct element of a public nuisance claims, the parties' summary judgment submissions revealed differing views on that. Plaintiffs argued that evidence proving unreasonable conduct is what the law requires—a standard this Court endorsed in its summary judgment ruling. ECF No. 1294 at 2 (holding that plaintiffs

[2] 5/3 Tr. at 22:1-5 (Plaintiffs' opening statement); *see also* ECF No. 1294 at 2-3 ("Plaintiffs acknowledge that they have to prove the unreasonableness of the alleged conduct ....").

must prove "the unreasonableness of the [defendant's] conduct"). While Defendants have framed the standard differently, this Court need not further engage on the debate for purposes of this motion—because Plaintiffs cannot meet their own version of the standard.[3]

THE EVIDENCE

There is no evidence of unreasonable conduct on the part of ABDC. The 14-year old Order to Show Cause and Immediate Suspension of Registration (ISO)—which related exclusively to a Florida distribution center that did not ship controlled substances to West Virginia and resulted in no fines or admission of liability—is the sole enforcement action DEA has ever taken against ABDC.[4] Indeed, Mr. Rannazzisi was left to say that, during his tenure at DEA, DEA had no "occasion to turn back to enforcement activities and investigation" of ABDC in the years following the Orlando ISO.[5] And there is no evidence of any such thing after Mr. Rannazzisi's tenure.

As for these jurisdictions specifically, there is no evidence whatsoever that ABDC ever failed to conduct adequate due diligence on its customers in Huntington and Cabell County;[6] failed to report a suspicious order made by a Huntington or Cabell County customer;[7] shipped a

[3] Plaintiffs' claims also fail for the independent and equally dispositive reason that they did not prove proximate causation. *See* Memorandum of Law in Support of Defendants' Motion for Judgment on Partial Findings Regarding Proximate Causation.

[4] *See* 5/19 Tr. at 36:2-18 (Mays); 6/8 Tr. at 72:6-10; 6/10 Tr. at 23:25-24:15 (Rannazzisi).

[5] 6/8 Tr. at 72:6-19, 83:23-84:14 (Rannazzisi). Moreover, after Plaintiffs' counsel questioned Mr. Rannazzisi at length on direct examination regarding inspections of distribution centers, he was unable to point to any inspection of Defendants' distribution centers that found a failure to maintain effective controls against diversion. 6/8 Tr. At 181:2-9 (Rannazzisi) ("Q. ... In conducting inspections of defendants' distribution centers during your tenure did DEA find the defendants failed to maintain effective controls against diversion? A. ... I don't recall. There were so many inspections in the distributor – the distributor population as a whole, yes, I'm sure they have, but I just can't recall if these three defendants had that type of, you know –.").

[6] *See generally* 6/8 Tr. at 72:6-10, 83:23-84:14 (Rannazzisi).

[7] Indeed, the record evidence shows that ABDC did report suspicious orders for Huntington and Cabell County customers. *See, e.g.*, P-44765; P-44766; P-44767.

suspicious order to a Huntington or Cabell County pharmacy;[8] shipped controlled substances to a Huntington or Cabell County pharmacy that was not registered with the DEA;[9] shipped controlled substances to a Huntington or Cabell County pharmacy that was a DEA-registered pharmacy that the DEA had warned ABDC not to supply,[10] or shipped a controlled substance into Huntington or Cabell County that was diverted.[11]

That is because, as explained below, ABDC always has maintained effective controls against diversion.

A. Between 1998 And 2007, ABDC Operated A Nationwide Suspicious Order Monitoring Program Approved By DEA[12]

1. Bergen Brunswig's Pre-1998 SOM Program And The Genesis Of The Work With DEA To Develop The 1998 Program

Prior to 1998, Bergen Brunswig operated a suspicious order monitoring (SOM) program that detected and reported suspicious orders to the DEA in two separate ways.[13] First, Bergen Brunswig developed a model Excessive Purchase Report.[14] The Report listed total customer purchases for the month that exceeded pre-determined multiples of the average monthly purchases

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[8] *See* 6/9 Tr. at 14:6–17 (Rannazzisi) (testifying that "he ha[d] not reviewed any documents related to West Virginia" and therefore could not identify "any orders in Huntington or Cabell County that [he] believed ... should have been blocked by one of the defendants but were not"); *see also generally* 6/8 Tr. at 72:6-10, 83:23-84:14 (Rannazzisi).

[9] 6/9 Tr. at 151:19-23 (Rannazzisi); 5/26 Tr. at 131:21-23 (Rafalski).

[10] 6/9 Tr. at 151:24-152:3 (Rannazzisi); 5/26 Tr. at 206:21-207:1 (Rafalski).

[11] *See* note 164, *infra*.

[12] ABDC refers to the program through which it monitors and reports suspicious orders to DEA as the "Order Monitoring Program" or "OMP." In this litigation, others have used the phrase "Suspicious Order Monitoring Program" or "SOM program" to refer to such programs. For clarity and consistency, this motion will use the phrase "SOM program." ABDC's SOM program (or OMP) is one aspect of ABDC's broader "diversion control" efforts (or "diversion control program"), which also includes new and ongoing customer due diligence, training, and policies and procedures.

[13] 5/13 Tr. at 174:6-16 (Zimmerman); AM-WV-00781 at 9.

[14] AM-WV-00781 at 9.

of Bergen Brunswig's total customer base.[15] Each of Bergen Brunswig's distribution centers sent Excessive Purchase Reports on a monthly basis to DEA field offices.[16] Second, Bergen Brunswig distribution center employees reported suspicious orders by telephoning their local DEA field office.[17] Bergen Brunswig made on average 12,000 calls annually to DEA field offices across the country reporting customer orders of controlled substances that it believed met the suspicious order criteria set forth in § 1301.74(b).[18] Nearly every order reported telephonically also was included in the month-end Excessive Purchase Report sent to DEA.[19]

During this period of time, some DEA field offices conveyed to Bergen Brunswig that they were "extremely upset" with the daily phone calls and told Bergen Brunswig to either limit the number of calls or report suspicious orders in a different way.[20] In response to this feedback from different DEA field offices, Mr. Zimmerman, on behalf of Bergen Brunswig, reached out to DEA to discuss implementation of a more efficient system for reporting suspicious orders—one that would benefit both the company and DEA.[21]

2. In 1998, Bergen Brunswig Developed A New Program For Identifying And Reporting Suspicious Orders, Which DEA Approved In Writing

On September 30, 1996 Mr. Zimmerman wrote to Thomas Gitchel, the Chief of the Liaison and Policy Section at DEA, suggesting that Bergen Brunswig work with DEA to develop a new

[15] AM-WV-00781 at 9.

[16] 5/13 Tr. at 174:6-16 (Zimmerman).

[17] 5/13 Tr. at 174:6-16 (Zimmerman).

[18] 5/13 Tr. at 47:3-24 (Zimmerman); AM-WV-00781 at 9.

[19] AM-WV-00781 at 9.

[20] 5/13 Tr. at 47:3-24 (Zimmerman); AM-WV-00781 at 9-10.

[21] 5/13 Tr. at 47:3-24 (Zimmerman); AM-WV-00781 at 9-12.

"suspicious order reporting program that would provide better quality information to DEA in a more efficient manner" by detecting and reporting suspicious orders electronically.[22]

ABDC's proposal to DEA detailed the type of information about the suspicious orders that was to be included in the Excessive Purchase Reports:

> The summary report would show the customer name, address, DEA Number, Item Description, NDC Number, Order Date, Active Ingredient Volume Ordered, Active Ingredient ***Shipped*** and Customer "Allowance" (i.e. average of customers' prior four months orders).[23]

On October 29, 1996, Mr. Gitchel responded to Mr. Zimmerman's proposal, confirming the information that would be included in the Reports:

> As proposed, the summary report would include the customer's name, address and DEA number; a description of the item ordered; the NDC number; date ordered; active ingredient volume ordered and ***shipped***; and the customer's "allowance" or average order."[24]

DEA also understood what information would ***not*** be included in the Report. Notably absent from the proposal was any suggestion that the Report would include any narrative explanation as to why any particular order was included on the Report, and DEA never requested that the Report include such information.[25] And the proposal also made clear that, as in the past, the orders identified on the Report already had been "shipped." In short, DEA understood what information would be contained in the Excessive Purchase Reports and that the orders included in these Reports had already been shipped.

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[22] AM-WV-00781 at 9-12.

[23] AM-WV-00781 at 10 (emphasis added).

[24] AM-WV-00781 at 7 (emphasis added).

[25] *See* AM-WV-00781 at 7-12.

For the next two years, Bergen Brunswig—working together with DEA—continued to develop and test the new SOM program.[26] Bergen Brunswig and DEA agreed that the new program would set thresholds that applied a default multiplier of three to a customer's four-month purchasing average.[27] But the new program "was completely flexible for however the DEA wanted to best utilize that information to prevent diversion."[28] To accomplish that, the program permitted, and Bergen Brunswig encouraged, DEA field offices to adjust the default multiplier for any given drug family, as needed.[29] DEA field offices also could adjust the frequency (daily, weekly, monthly, quarterly) of Bergen Brunswig's submission of Excessive Purchase Reports.[30]

During the testing phase, Bergen Brunswig made several changes to the proposed new SOM program at the direction of the DEA field offices that were participating in the testing.[31] However, DEA never told Bergen Brunswig that orders identified as suspicious should not be shipped:

> It took two years of working back and forth of what the report would look like, what would be the trigger points, what should we do. There was no discussion about stop shipping. There was never a discussion in those two-year processes. I worked with all the DEA offices. I worked with all the program managers. And I worked with Washington, DC. Never a reference to shop [*sic*] [stop] shipping.[32]

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[26] 5/12 Tr. at 219:9-13 (Zimmerman); AM-WV-00781 at 2-3, 7-8. Bergen Brunswig's Valencia distribution center began testing with the LA-DEA field office on March 1, 1997; Bergen Brunswig's Corona distribution center began testing with the Riverside DEA field office on April 1, 1997; Bergen Brunswig's Hawaii distribution center began testing with the Hawaii DEA field office May 1, 1997; and Bergen Brunswig's Orlando distribution center began testing with the Tampa DEA field office on June 1, 1997. *Id.* at 2.

[27] 5/13 Tr. at 55:1-17 (Zimmerman).

[28] 5/13 Tr. at 46:3-21 (Zimmerman).

[29] 5/13 Tr. at 55:1-17 (Zimmerman). Some field offices asked that the default multiplier to be doubled to six. *Id.* at 55:11-56:6 (Zimmerman).

[30] 5/13 Tr. at 46:3-21 (Zimmerman).

[31] AM-WV-00781 at 2-3.

[32] 5/13 Tr. at 49:3-10 (Zimmerman).

On July 23, 1998, Patricia M. Good, DEA's Chief of the Liaison and Policy Section of the Office of Diversion Control, officially approved the new nationwide SOM program.[33] She wrote to Bergen Brunswig stating:

> This is to grant approval of your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals, as required by Federal regulation.

DEA's approval is also highlighted at the bottom of the copy of the letter produced by DEA—which includes an internal DEA stamp stating "subject: approve suspicious order monitoring system":

cc: DPMs, OD/D, ODX
ODO _____
ODC _____
ODLP:McFaul____dt: 7-20-98 Document Name: Doc3.wpd
ffs: 601-04-R2 (1301.74)
subject: approve suspicious order monitoring system

AM-WV-02658

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DEA's letter lauded the new program's Excessive Purchase Reports, stating that "DEA managers who have been involved with the testing of the system have relayed their positive opinions regarding its ability to provide information in a fashion which is not only useful overall, but is also responsive to the needs of individual DEA offices."[34]

When Bergen Brunswig and Amerisource Health merged in 2001, the newly formed company—AmerisourceBergen—adopted and used the Bergen Brunswig DEA-approved SOM program across all of ABDC distribution centers nationwide until it enhanced the program in 2007.[35]

[33] AM-WV-00781 at 1 (ABDC-produced version); AM-WV-02658 (DEA-produced version).

[34] AM-WV-00781 (ABDC version); AM-WV-02658 (DEA produced version).

[35] 5/12 Tr. at 192:9-11 (Zimmerman); 5/17 Tr. at 189:1-10 (Mays).

3. Between 1998 And 2007, When ABDC Operated Its DEA-Approved Program Nationwide, DEA Never Told ABDC That Its Program Was Not Compliant Or Needed To Be Changed

The evidence is uncontroverted that that the SOM program Bergen Brunswig and then ABDC used between 1998 and 2007 never deviated from the program DEA approved in 1998. And the evidence also is uncontroverted that, between 1998 and April 2007, DEA never told ABDC that there were any problems with its SOM program or provided any guidance to ABDC that would have suggested that its program did not comply with ABDC's obligations under the Controlled Substances Act (CSA) to implement a program that provided effective controls against the diversion of controlled substances.

More specifically, prior to April 2007, DEA never told ABDC that it should not ship suspicious orders or that ABDC should enhance or otherwise modify its Excessive Purchase Reports.[36] There is no evidence controverting this point—and, indeed, the evidence confirms that—despite multiple opportunities to expressly and clearly do so over the years—DEA never provided such guidance.

a. Company Sponsored DEA Training Sessions

In the years following implementation of the DEA-approved SOM program, ABDC described its SOM program on numerous occasions at company-sponsored DEA training sessions. More specifically, between 2003 and 2005, Mr. Mays trained approximately 200 DEA diversion investigators at ABDC's Richmond, Virginia distribution center.[37] These training sessions, which included a tour of ABDC's distribution center and an ABDC-led presentation, educated future DEA

[36] *See, e.g.*, 5/13 Tr. at 196:19-22 (Zimmerman); 5/18 Tr. at 193:12-194:2, 195:12-196:2 (Mays).
[37] 5/18 Tr. at 164:17-165:4 (Mays).

diversion investigators about the wholesale pharmaceutical distribution industry and provided an exemplar of how registrants achieved and maintained regulatory compliance.[38]

Importantly, each training session included an overview of ABDC's DEA-approved SOM program, and described the program's timeframes (daily, weekly, monthly) for reporting suspicious orders.[39] DEA officials in attendance, including Thomas Prevoznik, never said anything critical of these reporting methods or otherwise indicated that they were inconsistent with the suspicious order regulation.[40] Mr. Mays gave this presentation at least five times over the course of 2003-2005—including in October 2005 (after the August 2005 DEA "Distributor Initiative" meeting discussed below)—and not once did anyone from DEA ever tell him that his presentation about suspicious order reporting was incorrect.[41] To the contrary, DEA conveyed its appreciation of ABDC's presentation and its willingness to help train future diversion control investigators and, in October 2004, the DEA presented ABDC with an award in recognition of its contribution to drug enforcement and to DEA's training program.[42]

b. August 2005 Distributor Initiative Meeting

In 2005, DEA convened individual meetings with distributors, referred to as the "Distributor Initiative." ABDC's meeting took place on August 10, 2005 at DEA headquarters in

[38] 5/18 Tr. 167:2-6 (Mays); *see also* AM-WV-00782 at 4-5; AM-WV-00785 at 4-5; AM-WV-00786 at 3.

[39] *See, e.g.*, AM-WV-00785 at 22.

[40] 5/18 Tr. at 183:9-20 (Mays) ("... I don't recall any of – in any of the sessions ever even being offered a recommendation or told to change anything or that anything was wrong.").

[41] 5/18 Tr. at 164:17-19, 183:9-20 (Mays).

[42] 5/18 Tr. at 180:23-181:14 (Mays) ("Q. Okay. And what was your understanding as to why they gave you an award? A. It was just to – it was in – you know, it was appreciation for all of the training that we had been doing over the years and during that specific time frame for the diversion investigators.").

Washington, D.C.[43] Mr. Mays participated for ABDC and Mike Mapes and Kyle Wright participated for DEA.[44] The meeting related exclusively to the growing internet pharmacy issue.[45] The meeting was cordial and cooperative.[46] DEA provided ABDC with information, materials, and suggested tools to help with investigations of possible illegal internet pharmacies.[47] The materials provided by DEA included a questionnaire entitled "Internet Pharmacy – Decision Questions," which consisted of twelve questions designed to help identify customers engaged in illegal internet activity.[48] While DEA did not mandate that ABDC include this questionnaire in its due diligence program, ABDC did so (as described below).[49]

Mr. Mays was the only meeting attendee who testified live at trial, and his testimony makes clear the meeting related only to internet pharmacies:

> Q. Okay. And, broadly speaking, what did you understand DEA's concerns to be that they raised to you during this meeting?
>
> A. ***It was exclusively about internet pharmacy*** and the problem that they were having with internet pharmacies.[50]

DEA did not indicate that ABDC had failed, or was failing, to meet its regulatory obligations (as they relate to internet pharmacies or otherwise).[51] In fact, DEA did not say anything to ABDC about its SOM program in general, let alone tell ABDC that it should revise its programs or policies, or even that it was required to implement the tools related to internet pharmacies DEA

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[43] P-09112 at 1.

[44] P-09112 at 1.

[45] 5/18 Tr. at 193:1-5 (Mays).

[46] 5/18 Tr. at 196:1-2 (Mays) ("Very cordial, cooperative. I didn't take it as adversarial at all.").

[47] AM-WV-01079 at 1; 5/18 Tr. at 193:6-194:18 (Mays).

[48] P-09112 at 17-18.

[49] 5/18 Tr. at 194:9-18, 198:25-199:12 (Mays).

[50] 5/18 Tr. at 193:1-5 (Mays) (emphasis added).

[51] 5/18 Tr. at 195:12-196:2 (Mays).

discussed at the meeting.[52] And DEA never suggested that ABDC should not ship suspicious orders.[53]

Mr. Mays testified that if DEA had raised any such issues or concerns, he would have immediately shared that message to his colleagues and initiated an action plan:

> I mean, I would have gone back and like, you know, rung the alarm bells if they brought me to DC and told – to their offices and told me we were doing something wrong, yes, I would have – we would have made immediate changes to correct it.[54]

ABDC followed up with DEA through a September 19, 2005 conference call that included Mr. Mays, Mr. Mapes, and others from ABDC.[55] Mr. Mays explained that the company had begun developing procedures to address the problem of illegal internet pharmacy sales.[56] Like the August 10, 2005 conversation, this discussion related only to internet pharmacies; DEA did not say anything suggesting that it believed ABDC was failing to meet its regulatory obligations.[57]

The documentary evidence corroborates Mr. Mays' testimony about the distributor initiative meeting. His contemporaneous written summaries of the August 10, 2005 meeting and September 19, 2005 conference call corroborate his trial testimony.[58] Mr. Mapes' contemporaneous written summary of the August 10, 2005 meeting likewise corroborates Mr. Mays' testimony.[59] That summary, which lists the topics addressed and issues discussed at the meeting, makes ***no*** mention of any discussion of ABDC's method of reporting suspicious orders

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[52] *See generally* 5/18 Tr. at 193:1-196:2 (Mays); P-09112 at 1-2; AM-WV-01079 at 1.

[53] 5/18 Tr. at 193:12-194:2 (Mays).

[54] 5/18 Tr. at 195:20-24 (Mays).

[55] AM-WV-01079 at 1; 5/18 Tr. at 198:3-9 (Mays).

[56] AM-WV-01079 at 1.

[57] 5/18 Tr. at 198:3-24 (Mays).

[58] AM-WV-01079 at 1.

[59] P-09112 at 1-2.

or practice of shipping suspicious orders and confirms that the only topic discussed at the meeting was internet pharmacies.[60]

Mr. Rannazzisi repeatedly referred to "the distributor initiative meetings" in his trial testimony when asked if and when distributors were provided guidance indicating that they should not ship suspicious orders and that the excessive purchase reports distributors were sending to DEA were not "suspicious order reports.[61] There is no evidence at all that supports these self-serving assertions. To begin with, Mr. Rannazzisi admitted that he did not attend the DEA's distributor initiative meeting with ABDC.[62] Moreover, he said that he would expect Mr. Mapes' summary to be comprehensive and list all topics and issues discussed at the meeting.[63] Mr. Mapes' summary says nothing about the practice of shipping suspicious orders or the adequacy of excessive purchase reports.[64] Mr. Rannazzisi's generalized assertions—made more than 15 years after-the-fact and concerning a meeting he did not attend—cannot override Mr. Mays' uncontroverted testimony and the corroborating contemporaneous documentary evidence.[65]

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[60] P-09112 ("The purpose of the meeting was to address illegal domestic internet pharmacy problem and their source of supply.").

[61] *See, e.g.*, 6/8 Tr. at 63:9-16, 103:10-19 (Rannazzisi); 6/9 Tr. at 34:10-21; 83:1-5; 230:11-14 (Rannazzisi).

[62] 6/10 Tr. at 9:24-10:1 (Rannazzisi).

[63] 6/9 Tr. at 210:15-25 (Rannazzisi) ("I would expect that Mr. Mapes would do a complete memo including everything else in – that happened during the meeting.").

[64] P-09112 at 1-2.

[65] As for his testimony about excessive purchase reports, Mr. Rannazzisi never could explain exactly what he thought the reports should have contained (beyond declaring that the reports distributors were sending were unhelpful and that the reports should have explained "why" an order was suspicious). Nor could he point to anything in the regulations that aligned with his view. 6/9 Tr. at 59:11-17 (Rannazzisi). And while he said that his "Dear Registrant" letters contained guidance on the matter and that "it was discussed in the distributor initiative briefings" (6/7 Tr. at 233:19-23 (Rannazzisi)), there is no evidence substantiating those assertions. The September 27, 2006 letter says nothing at all about excessive purchase reports. *See* P-00032 at 9-12. And, while the December 2007 letter does say something about such reports (P-00032 at 3-4), by the time it was sent, ABDC already had implemented its enhanced diversion control program. It no longer

Other undisputed evidence also shows that the distributor initiative meeting related only to internet pharmacies. Following the meeting, ABDC developed and implemented CSRA 2.12: Possible Excessive/Suspicious Order Review—a new robust policy to help DEA with the growing illegal internet pharmacy problem.[66] ABDC utilized its Form 590 (a customer questionnaire), which included ***every*** question in DEA's suggested "Internet Pharmacy – Decision Questions" questionnaire.[67] ABDC and DEA worked collaboratively to uncover and shut down numerous pharmacies engaged in illicit internet activity.[68]

In short, the overwhelming evidence shows that ABDC took action to address the internet pharmacy issue. ABDC considered recommendations from DEA, incorporated those recommendations and revised its policies almost immediately, and then put those revised policies into action in real time by opening investigations into customers potentially involved in illicit internet activity. DEA asked for ABDC's help with this issue in August 2005, and the company promptly complied.[69]

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utilized excessive purchase reports—instead, suspicious orders were reported to DEA and not shipped. Thus, when ABDC received the December 2007 letter, its suspicious order monitoring and reporting practices aligned with what the letter suggested.

[66] 5/18 Tr. at 198:25-205:23 (Mays); AM-WV-01079 at 1-11.

[67] 6/10 Tr. at 19:8-23 (Rannazzisi). ABDC's Form 590 also incorporated several additional questions not included in DEA's suggested "Internet Pharmacy – Decision Questions" questionnaire. *Id.*; *see also* AM-WV-01079 at 10-11.

[68] *See* 5/18 Tr. at 201:21-202:14 (Mays).

[69] As part of this new policy, ABDC also undertook thorough investigations of other customers, investigating hundreds of customers between October 2005 and August 2007. 5/19 Tr. at 8:1-7 (Mays). ABDC investigators validated registrations and analyzed customers' one-year controlled substance purchase reports, site visit results, photos, Form 590 Questionnaires, and all publicly available documents. AM-WV-01079 at 4-6; 5/18 Tr. at 202:20-205:23 (Mays). Nine of the customers investigated were pharmacies located in Cabell-Huntington. *See* AM-WV-00714A. ABDC found no indication of diversion for any of these nine pharmacies. *Id.* DEA did not require ABDC to undertake any of these measures—instead, ABDC did so voluntarily. 5/18 Tr. at 199:13-20 (Mays).

c. 2006 "Dear Registrant" Letter

On September 27, 2006, Mr. Rannazzisi sent all distributors, including ABDC, a letter addressed simply to "Dear Sir or Madam."[70] Plaintiffs—and Mr. Rannazzisi—have tried to suggest that the letter provided some sort of notice to distributors that there were deficiencies in their SOM programs. The letter, however, does not support that assertion. The letter did not say that excessive purchase order reports were not the type of suspicious order reports required by the regulations; and it does not say that distributors should not ship suspicious orders.

Nor did the letter say anything that would suggest that DEA was withdrawing its approval of ABDC's 1998 program or that there was something wrong with its approved SOM program. Mr. Zimmerman explained why he reasonably believed that a "Dear Registrant" letter—which was not addressed specifically to ABDC, but instead distributors generally—did not override DEA's 1998 written approval of ABDC's SOM program or provide a basis for ABDC to believe it needed to modify that program:

> So I worked with the DEA from '96 to '98 to devise a suspicious order reporting program. I worked with them for two years. And we worked with the different offices and we created a suspicious order report that shipped orders after they were identified. It was signed off by the program managers of the DEA. It was signed off on by the chief of the diversion unit at DEA. And that was the program that we had in place at this time. Now, I can take my two years of work and a letter from the chief of the diversion unit or a letter that's not even addressed to us. It just says "registrant." I'm going to go with my two years of work. And never once did they mention what they felt their interpretation was because their interpretation was you do ship the order. And all I could – so I'm going to go with my two years and approved letter versus an unregistered letter.[71]

Moreover, Mr. Rannazzisi's letter stated that "DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent

[70] P-00032 at 9-12.

[71] 5/12 Tr. at 219:9-25 (Zimmerman).

diversion."[72] That assertion, coupled with the fact that the letter said nothing about a "no ship" requirement or offered any criticism of the use of excessive purchase reports, undermines any conclusion that the letter put ABDC on notice that there was anything wrong with its approved SOM program.

B. In Response To Guidance From DEA, ABDC Enhanced Its Diversion Control Program In 2007, And DEA Effectively Approves The Program

1. ABDC Worked With DEA To Develop An Enhanced Diversion Control Program And Resolved The ISO Without Admitting To Any Wrongdoing Or Paying A Fine

On April 19, 2007, DEA issued an ISO for ABDC's Orlando, Florida distribution center.[73] The focus of the ISO was narrow—pertaining to ABDC's Orlando distribution center's distribution of controlled substances to four Florida customers engaged in illicit internet pharmacy activity.[74] The ISO was specific to ABDC's Orlando distribution center, which did not ship controlled substances to West Virginia.[75] And the ISO did not relate to, nor affect, ABDC's distribution of controlled substances from any other distribution center, including the distribution center in Lockbourne, Ohio that serviced the Cabell-Huntington area.[76]

The ISO came without warning and was a complete surprise to ABDC—particularly given ABDC's collaborative relationship with DEA over the years, including the joint effort to address the illegal internet pharmacy issue in the months prior.[77] According to Mr. Mays, it also came as a complete surprise to DEA's Mike Mapes, who had met with Mr. Mays at the August 10, 2005

[72] P-00032 at 10.

[73] P-00049.

[74] *See* P-00049; *see also* 5/19 Tr. at 23:2-16 (Mays).

[75] 5/13 Tr. at 190:25-191:3 (Zimmerman).

[76] 5/19 Tr. at 23:2-16 (Mays).

[77] 5/19 Tr. at 21:7-25 (Mays).

internet pharmacy distributor initiative meeting (and who DEA assigned to later work with ABDC).[78]

Moreover, following the August 10, 2005 distributor initiative meeting and prior to April 19, 2007, DEA never once indicated to ABDC that it was displeased with ABDC's efforts to address the illegal internet pharmacy problem.[79] In fact, ABDC had already cut off supplying controlled substances to three of the four pharmacies named in the ISO.[80]

On April 27, 2007, just three days after it served the ISO, DEA issued an Order of Special Dispensation and Agreement that permitted the Orlando distribution center to ship controlled substances to hospitals, clinics, the Department of Defense, and a limited number of other customer accounts.[81] DEA also was aware that ABDC had obtained a license on an expedited basis from the Florida Department of Health that enabled the Lockbourne, Ohio distribution center to resume servicing ABDC's Florida accounts with controlled substances.[82]

Shortly after the ISO was served, ABDC met with DEA in Washington, D.C. on April 25, 2007.[83] DEA informed ABDC that it wanted ABDC to implement a program that blocked and did not ship the orders it identified as suspicious.[84] This was the ***first time*** DEA had provided such a directive.[85] Before this point in time, DEA had not offered any guidance regarding a registrant's

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[78] 5/19 Tr. at 21:7-25 (Mays).

[79] 5/19 Tr. at 19:20-24, 21:7-25 (Mays).

[80] 5/12 Tr. at 225:9-21 (Zimmerman); 5/13 Tr. at 192:16-21 (Zimmerman).

[81] 5/19 Tr. at 23:23-24:17 (Mays); P-00009 at 1.

[82] 5/19 Tr. at 24:18-25:24 (Mays).

[83] 5/19 Tr. at 26:4-17 (Mays).

[84] 5/19 Tr. at 26:18-27:3 (Mays).

[85] *See, e.g.*, 5/19 Tr. at 26:23-27:19 (Mays); *see also Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 222 (D.C. Cir. 2017) (noting that "DEA ***first*** articulated that [do not ship] requirement in *Southwood*," an administrative decision)(emphasis added); P-23736 (72 Fed. Reg. at 36,501)); 6/9 Tr. at 46:10–18 (Rannazzisi confirming that DEA's guidance "was announced in

obligations regarding suspicious orders that differed from ABDC's DEA-approved program—that is, DEA has never informed ABDC that it should not be shipping suspicious orders or that Excessive Purchase Reports were an insufficient means to report suspicious orders.[86] *See* Section A.3, *supra*.

Between April 19 and June 22, 2007, ABDC worked hand-in-hand with DEA to develop an enhanced diversion control program.[87] ABDC and DEA had regular meetings at DEA headquarters.[88] And DEA personnel were on-site at ABDC's headquarters working alongside personnel from ABDC's Corporate Security and Regulatory Affairs (CSRA) for weeks in order to assist with the development of the new diversion control program.[89] ABDC, with direct input and oversight from DEA, designed every aspect of the enhanced SOM program—including customer types, customer sizing, drug product families, peer groups, and use of multipliers.[90]

While on site, DEA personnel also provided additional input and guidance. Mr. Mapes, Mr. Wright, and Mr. Davis, at ABDC's request, reviewed due diligence files for several of its high-volume accounts—at least one of which was located in West Virginia—so that DEA could to advise whether these files raised any concerns that would justify ABDC cutting off these customers or warrant referral to DEA for investigation.[91] DEA never indicated to ABDC that any of these due diligence files were deficient.[92] Nor did DEA indicate that ABDC's decisions to continue servicing

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the final order [in *Southwood*], yes, at that point in time"); 5/26 Tr. at 255:6-96 (Rafalski testifying that "do not ship" guidance "do[es] not appear anywhere in the statute or the regulations").

[86] *See, e.g.*, 5/13 Tr. at 196:19-22 (Zimmerman); 5/18 Tr. at 193:12-194:2, 195:12-196:2 (Mays).

[87] 5/19 Tr. at 29:3-30:2 (Mays).

[88] 5/19 Tr. at 26:10-28:5 (Mays).

[89] 5/19 Tr. at 29:3-24 (Mays).

[90] 5/19 Tr. at 45:3-46:8 (Mays).

[91] 5/19 Tr. at 30:11-23 (Mays).

[92] 5/19 Tr. at 31:2-17 (Mays).

those customers—including the West Virginia customer—were flawed or questionable. To the contrary, DEA told ABDC that it had done everything it could have done in terms of due diligence for these customers, including for certain "high volume" customers.[93]

DEA and ABDC resolved the Orlando matter through a Settlement and Release Agreement in very short order—a little more than two months after the ISO was served—on June 22, 2007.[94] The Agreement did not include any fine or financial penalty.[95] The Agreement stated that it was not "an admission of liability by AmerisourceBergen" and "AmerisourceBergen expressly denies the DEA's allegations."[96] The Agreement required ABDC (with DEA's input and guidance) to design and implement a new diversion control program, including an enhanced SOM program that would—for the first time in this industry—block and not ship suspicious orders. *See* Section B.2, *infra*.

The Agreement further required that that the Orlando distribution center's DEA-registration would be reinstated only after DEA "conduct[ed] reviews of the functionality of AmerisourceBergen's diversion compliance program ("Compliance Reviews") at up to five distribution centers of AmerisourceBergen."[97] The Compliance Reviews and audits were thorough—taking several days to complete and including DEA's review of the order review process at the distribution center level.[98] DEA also audited ABDC's order review process at the

[93] 5/19 Tr. at 30:11-31:13 (Mays).

[94] P-00009.

[95] P-00009; 5/19 Tr. at 36:2-5 (Mays).

[96] P-00009 at 1; 5/19 Tr. at 36:6-8 (Mays).

[97] P-00009 at 3.

[98] 5/19 Tr. at 34:1-11 (Mays) ("They – basically, we walked them through the whole process of how an order hits their system, if it exceeds threshold, what the DC does with it, then how it gets sent to corporate, and then they could see that whole process about whether the order, you know, whether – they saw the whole process of an order being released or an order being rejected and reported as suspicious.").

corporate level, looking, for instance, at the due diligence documents investigators relied on when adjudicating orders.[99] Each of these Compliance Reviews passed muster and, as a result, DEA permitted ABDC to file a renewal application for the Orlando distribution center's registration—and DEA renewed the registration in August 2007.[100]

2. ABDC's Enhanced Diversion Control Program Was Effectively Approved By DEA In 2007

Given DEA's extensive involvement in the design and implementation of ABDC's enhanced diversion control program (including its enhanced SOM program), ABDC understood that DEA's return of the Orlando distribution center registration signaled effective approval of ABDC's enhanced program.[101]

DEA's approval and endorsement of ABDC's 2007 diversion control program was further confirmed at the DEA's own Pharmaceutical Industry Conference in Houston, Texas on September 11-12, 2007.[102] There, Mr. Zimmerman, alongside DEA's Mr. Mapes, made a presentation to the industry on ABDC's enhanced diversion control program.[103] ABDC understood that DEA viewed ABDC's new enhanced program as the industry standard, and DEA wanted other distributors to implement the same or similar program—and DEA's own website confirms this.[104] ABDC gave

[99] 5/19 Tr. at 34:15-35:2 (Mays) ("They would look – they could look on the screen to see how the investigator was handling the orders. They knew the options the investigator had. They would see what they would look at, the types of documents and records and history that they would look at.").

[100] 5/19 Tr. at 35:17-36:1 (Mays); 6/10 Tr. at 29:3-30:4 (Rannazzisi).

[101] 5/19 Tr. at 38:22-39:7 (Mays).

[102] *See generally* DEF-WV-02191 (DEA website); DEF-WV-00001.

[103] 5/13 Tr. at 198:7-205:15 (Zimmerman); DEF-WV-00001.

[104] DEF-WV-02191 (DEA website); DEF-WV-00001; 5/19 Tr. at 40:7-12 (Mays); 5/20 Tr. at 157:6-158:5 (Mone – Cardinal Health) ("Q. Now, what is your understanding of what happened at the conference? A. My understanding of what happened at the conference was that a competitor had presented in conjunction with the DEA and explained their new electronic system for reporting

this same presentation in 2009 when DEA asked ABDC to join it at a conference to explain how the program was functioning.[105]

It also is worth noting that the presentation at the 2007 conference confirms that DEA understood that ABDC had been shipping suspicious orders before it implemented its 2007 SOM program. Mr. Zimmerman and Mr. Mapes' presentation on ABDC's new program emphasized DEA's ***new*** interpretation of the suspicious order regulations. Specifically, Mr. Zimmerman and Mr. Mapes reviewed the industry's shift away from the historical "ship and report" approach, explaining that distributors had been reporting suspicious orders ***after*** they had been shipped and were now identifying, investigating and reporting suspicious orders ***before*** they were shipped.[106]

Neither Mr. Mapes, nor anyone else from DEA, ever took issue with Mr. Zimmerman's description of past practices.[107]

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suspicious orders and that the expectation of the DEA had changed relative to when Suspicious Order Reports would be sent to DEA.").

[105] 5/13 Tr. At 205-206; DEF-WV-00002 (2009 presentation).

[106] DEF-WV-00001; DEF-WV-02191 at 2.

[107] 5/13 Tr. at 205:16-24 (Zimmerman); 6/10 Tr. at 35:4-24 (Rannazzisi). Other evidence confirms that DEA's 2007 request that ABDC block and not ship suspicious orders reflected ***new*** guidance. For instance, changes made in 2009 to DEA's Diversion Investigators Manual—an internal

3. ABDC's 2007 Enhanced Diversion Control Program

ABDC implemented its enhanced diversion control program nationwide in June 2007.[108] Most notably, the program rejected and did not ship suspicious orders.[109] The 2007 program consisted of five "buckets" of activities that monitor suspicious orders and guard against diversion,[110] which continue to be the cornerstones of the program through present day.[111]

***Enhanced suspicious order monitoring program*:** ABDC's enhanced program, as effectively approved by DEA, monitors and reports suspicious orders as follows: ABDC created peer groups so it could compare like customers to like customers—*i.e.*, retail to retail, hospital to hospital.[112] ABDC organized controlled substances into drug families, and "sized" customers into

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document used by DEA's investigators, which is not available to registrants—confirm that ***prior*** DEA guidance did not require distributors to block and not ship suspicious orders. *See* 6/9 Tr. at 28:23-29:2 (Rannazzisi). DEA issued a Manual in 1997 and it remained in effect until 2009, when DEA revised it. 6/9 Tr. at 22:2-31:11 (Rannazzisi). The 1997 Manual (a) did not say that distributors should not ship suspicious orders; (b) did not require distributors to conduct additional due diligence for orders exceeding thresholds before determining whether an order is suspicious; (c) did not require distributors to report suspicious orders when discovered; and (d) did not advise against or otherwise discredit distributors' excessive purchase reports. P-08861 at 10-12. *See* DEF-WV-03842 (Rannazzisi's October 27, 2009 memorandum attaching revised "interim guidelines" and indicating that the Office of Diversion Control was continuing the process of "re-writing the Diversion Manual"); 6/9 Tr. at 29:7-31:11 (Rannazzisi). Revisions to the guidelines included the addition of a "no ship" requirement and new disapproval of excessive purchase reports. *See* 85 Fed. Reg. 69282, RIN 1117–AB47. Moreover, in 2020, DEA sought to amend the CSA's implementing regulations to include, for the first time, a "no-shipping" requirement. *See id*. at 69288. That proposed amendment would not have been necessary if the regulations already included such a requirement. *See* ECF No. 1158 (Defendants' Notice of Supplemental Authority in Opposition to Plaintiffs' Motion for Partial Summary Judgment Concerning Defendants' Statutory and Regulatory Duties).

[108] Thus, ABDC already had stopped shipping orders identified as suspicious ***before*** Mr. Rannazzisi sent his December 2007 "Dear Registrant" letter—which Plaintiffs say put distributors on notice of the "no ship" guidance. *See* P-00032 at 3.

[109] 5/19 Tr. at 31:18-32:18 (Mays).

[110] 5/17 Tr. 29:2-30:12 (May).

[111] *Id.*

[112] *See* 5/17 Tr. at 85:6-86:13 (May).

small, medium, or large.[113] ABDC also created new thresholds for each type and size of customer for each drug family, using a multiplier of three for ARCOS-reportable controlled substances.[114] A computer program processes all controlled substances orders to determine if they exceeded the customer's threshold for that particular drug family.[115] Orders that hit the thresholds—considered "orders of interest"—are subject to human review and evaluation (using a totality of circumstances test comprised of many factors) to determine if the order met the statutory definition of "suspicious."[116] If the order is deemed suspicious, it is reported to DEA and is not shipped.[117]

***New Customer Due Diligence*:** ABDC required all new pharmacy customers, except for chain customers, to complete a Form 590 during an on-site visit.[118] After that, a CSRA (diversion control) team member reviewed and verified the customer's responses.[119]

***Ongoing Customer Due Diligence*:** ABDC implemented a "Do Not Ship List," which includes customers to which ABDC will no longer ship controlled substances and customers ABDC declined to onboard after new customer due diligence investigations.[120] Customers are added to the List as a result of information ABDC learned either through its own investigations or through other sources.[121] Since 2007, ABDC has added almost 800 customers to its "Do Not Ship List" nationwide.[122] CSRA also communicates directly with a customer to inquire about its

[113] 5/17 Tr. at 86:15-87:24, 203:21-204:4 (May).
[114] *See generally* 5/17 Tr. at 203:14-204:4 (May).
[115] 5/17 Tr. at 31:14-32:9 (May).
[116] 5/17 Tr. at 31:14-32:9, 36:11-39:6 (May).
[117] *See* 5/17 Tr. at 39:7-40:5 (Mays).
[118] *See* DEF-WV-02191 at 2 (DEA website); 5/19 Tr. at 38:13-18 (Mays).
[119] *See generally* 5/19 Tr. at 19:14-16 (Mays).
[120] 5/17 Tr. at 120:1-13 (May).
[121] *See generally* AM-WV-00601.
[122] *See generally* AM-WV-00601.

purchasing history or conducts a site visit.[123] And CSRA holds weekly meetings to analyze the previous week's suspicious orders, including the drug family, quantity, and other metrics related to each suspicious order.[124]

***Policies and Procedures*:** ABDC revised and supplemented its policies and procedures to reflect the enhancements it made to its diversion control program in 2007.[125] When ABDC has made subsequent revisions to the program, its policies and procedures were revised accordingly.[126]

***Training*:** ABDC trains all employees involved in the Diversion Control Program, including associates at the distribution center and CSRA diversion control investigators.[127] ABDC also trains its sales staff.[128] Since 2007, training programs have been revised and enhanced to reflect the changes in ABDC's diversion control program.[129]

C. ABDC Continues To Take A Proactive Approach And Constantly Reviews, Adjusts, And Enhances It Diversion Control Program

In March 2014, ABDC hired David May, a 30-year veteran of the DEA.[130] Mr. May has oversight of the day-to-day management of the ABDC's Diversion Control Team.[131] He also has primary responsibility for and oversight of all interactions with the DEA and state regulatory bodies as related to diversion control and suspicious order monitoring.[132]

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[123] 5/17 Tr. at 26:23-27:16 (May).
[124] 5/17 Tr. at 39:15-40:5 (May).
[125] 5/17 Tr. at 28:2-14 (May).
[126] 5/17 Tr. at 28:2-14 (May).
[127] 5/17 Tr. at 28:16-29:1 (May).
[128] 5/17 Tr. at 28:16-29:1 (May).
[129] *See generally* 5/17 Tr. at 74:9-23 (May).
[130] 5/14 Tr. at 16:2-17:2 (May).
[131] *See* 5/14 Tr. at 16:2-17:2 (May).
[132] *See* 5/14 Tr. at 20:20-22:14 (May)

In 2014, ABDC began using Pharma Compliance Group, a compliance consulting company made up of former DEA diversion investigators and special agents, for certain pharmacy audits and investigations.[133] Also in 2014, ABDC engaged FTI Consulting to evaluate its diversion control program, including its SOM program.[134] ABDC sought to identify a more comprehensive, user-friendly way to best utilize the data it collected from customers both for adjudicating orders and conducting due diligence.[135] Between 2014 and 2015, ABDC and FTI developed, tested, and refined enhancements to ABDC's SOM program.[136] The resulting Revised SOM program (typically referred to by ABDC in the normal course as the "Revised OMP") incorporated user-friendly dashboards that visually present many advanced analytics, including customers' purchase history, and trends and developments related to drug use at the national, state, and local levels.[137] Dashboards are supported by essentially the same voluminous amounts of information and data that has been available to CSRA investigators since 2007; the presentation of this data allows diversion investigators to make better decisions in both order adjudication and ongoing customer due diligence efforts.[138]

On May 25, 2018, ABDC requested a meeting with DEA to discuss how ABDC's Revised SOM program could "better serve the diversion control objectives of the Drug Enforcement Administration ("DEA") and combat the opioid crisis."[139] With two complete years of data behind the 2015 enhancements to the SOM program, ABDC believed it was an appropriate time to meet

[133] 5/14 Tr. at 55:23-56:22 (May).
[134] 5/14 Tr. at 54:18-55:14, 63:18-64:3 (May).
[135] *See generally* 5/14 Tr. at 54:18-55:14, 67:20-25 (May).
[136] 5/14 Tr. at 54:18-55:14 (May).
[137] *See, e.g.*, 5/17 Tr. at 50:10-55:11, 58:8-63:22, 65:8-68:13 (May).
[138] *See, e.g.*, 5/17 Tr. at 93:25-94:17 (May).
[139] AM-WV-00640.

with the DEA to review the results of the enhancements and "determine the suspicious order reporting approach which best serves the diversion control objectives of the DEA."[140] Although DEA initially agreed to meet with ABDC and review its Revised SOM program, DEA subsequently cancelled and never rescheduled.[141]

ARGUMENT

I. Plaintiffs Have Not Proved Culpable Conduct: Unreasonable Conduct

A. The Evidence Relating To ABDC's Diversion Control Program Does Not Establish Unreasonable Conduct

Far from proving unreasonable conduct on the part of ABDC, the evidence shows that ABDC always has taken its diversion control responsibilities seriously and always has operated a SOM program approved by DEA and in accordance with what the law requires. In 1998, DEA granted express written approval of Bergen Brunswig's (ABDC's predecessor) nationwide SOM program. That approval was the culmination of two years of work by Bergen Brunswig—working together with DEA—to develop and test the new program. When DEA approved the program, it knew that orders identified as suspicious were shipped to customers and then reported to DEA in an excessive purchase report. Bergen Brunswig, and then ABDC, operated this DEA-approved SOM program on a nationwide basis until April 2007, when ABDC enhanced its SOM program, again with DEA's specific guidance and then approval. There is no evidence to the contrary. *See* Section A.1 & 2, *supra*.

The gist of Plaintiffs' liability theory—conveyed chiefly through the testimony of former DEA official Mr. Rannazzisi—is that, starting in 2005, DEA informed distributors (i) that the reports on suspicious orders (*i.e.*, the excessive purchase reports) they had been providing to DEA

[140] AM-WV-00640.

[141] 5/17 Tr. at 93:10-93:16 (May).

were insufficient and (ii) that distributors should not ship suspicious orders. But there is no evidence—from Mr. Rannazzisi or otherwise—that DEA provided any such guidance (or even a made a suggestion along those lines) to ABDC before April 2007. *See* Section A.3, *supra*.

In April 2007—when DEA for the ***very first time*** informed ABDC that it should not ship suspicious orders—ABDC made modifications to its SOM program to comply with that request. As it had when developing its 1998 program, ABDC worked closely with DEA to develop its diversion control program in 2007—and DEA effectively approved that program too. There is no evidence to the contrary on any of this either. *See* Section B, *supra*.[142]

The evidence further shows that ABDC has continued to enhance its diversion control program in the following years. It enhanced its program in 2014, and it has done an annual "refresh" of its program every year since then to implement program adjustments and technological advancements. The evidence on this too is uncontroverted. *See* Section C, *supra*.

The very brief suspension order in 2007 related to ABDC's Orlando distribution center—which did ***not*** ship controlled substances to customers in Cabell and Huntington—cannot support a finding of unreasonableness. This single incident more than 14 years ago was quickly resolved—with ABDC working closely with DEA—without a finding or admission of liability and without the imposition of a fine.

After that, there is ***absolutely nothing***—even Plaintiffs' witness Mr. Rannazzisi expressly said so. There is no evidence whatsoever that DEA ever determined that ABDC engaged in

[142] And, while Plaintiffs tried to establish what Defendants should have done (and should not have done) through Mr. Rannazzisi's testimony, the record shows that ABDC's post-2007 program functioned in a manner consistent with the views Mr. Rannazzisi offered at trial: ABDC holds orders that exceed thresholds, and conducts further due diligence to determine if the order is "suspicious" and does not ship the order if it is. *See, e.g.*, 5/13 Tr. at 194:21-195:2 (Zimmerman); DEF-WV-00001 at 9-16; 5/17 Tr. at 35:18-36:13 (May).

conduct warranting an investigation or enforcement action. And as for Cabell and Huntington specifically, there is no evidence that ABDC failed to conduct adequate due diligence on its customers in Huntington and Cabell County, or shipped a suspicious order to a Huntington or Cabell County customer, or shipped controlled substances to a Huntington or Cabell County customer that was not registered with the DEA, or shipped controlled substances to a DEA-registered customer in Huntington or Cabell County that the DEA had warned ABDC not to supply. *See* p. 8, *supra*.

In short, the evidence relating to ABDC's diversion control efforts does not prove culpable conduct—that is, unreasonable conduct—on the part of ABDC.

B. The Testimony Of Plaintiffs' Diversion Control Expert Does Not Prove Unreasonable Conduct

The testimony of Plaintiffs proffered expert witness Mr. Rafalski does not establish unreasonableness either.[143] His "opinion" that Defendants should have reported more orders, and correspondingly should have shipped fewer orders, is not based on a reliable methodology or real world facts. And while Mr. Rafalski purports to have an opinion that Defendants' SOM programs are "flawed," that opinion is nothing more than *ipse dixit*. He never explained how or why ABDC's (or, for that matter, any other Defendants') suspicious order monitoring systems and policies were

[143] The flaws in Mr. Rafalski's methodology and analysis is explained in more detail elsewhere. *See* ECF No. 1386, ECF No. 1398, ECF No. 1405, and ECF No. 1418. A court may enter judgment as a matter of law if, after applying the standards for expert testimony established in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny, it determines that an expert's testimony is unreliable or speculative and thus provides no basis for the jury to find in favor of the non-movant. *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict."); *see also Weisgram v. Marley Co.*, 528 U.S. 440, 445-46 (2000) (affirming conclusion that defendant's motion for judgment as a matter of law should have been granted where testimony of plaintiffs' expert witness was "speculative and not shown to be scientifically sound").

deficient, or explained how or why the thresholds used by ABDC to monitor for suspicious orders were set improperly, or identified any other concrete issue with the programs. Mr. Rafalski's testimony therefore cannot support a judgment against ABDC.

Indeed, Plaintiffs' efforts to prove their case based on both Mr. Rannazzisi's testimony and Mr. Rafalski's testimony reveals the flaws in the case. What these witnesses had to say about the methods that should be used to identify and report suspicious orders, as well as the number of orders that should have be identified as suspicious, cannot be reconciled. Mr. Rannazzisi testified that distributors should not use an overly mechanical numerical threshold without consideration of real-world circumstances (such as the location of the pharmacy in relation to hospitals and health care facilitates) to identify suspicious orders.[144] But Mr. Rafalski's flagging methodologies represent just such a mechanical exercise.[145] Mr. Rannazzisi's and Mr. Rafalski's views on the outcome that a proper (according to each of them) analysis of orders should yield also differ dramatically. According to Mr. Rannazzisi, "the volume of suspicious orders that should come in is not a huge quantity of orders. It shouldn't be like boxes of orders."[146] Yet, Mr. Rafalski's flagging methodologies purported to identify literally millions of orders as suspicious and he concluded nearly of 90% of all orders received by Defendants were "suspicious."[147]

C. The Absence Of DEA's Guidance Underscores That Plaintiffs Cannot Prove Unreasonable Conduct

Evidence of ABDC's conduct is only part of the story. What DEA did and did not say over the years is critical to the assessment of whether Plaintiffs have established unreasonable conduct

[144] *See* 6/8 Tr. at 111:11–24, 183:22–184:2 (Rannazzisi).

[145] 5/26 Tr. at 84:12–95:21, 96:10–16, 97:7–12, 231:9–14 (Rafalski).

[146] 6/7 Tr. at 219:15–17 (Rannazzisi).

[147] 5/26 Tr. at 96:17–97:6 (Rafalski).

on the part of ABDC. That evidence revealed DEA's guidance was vague, shifting, and often entirely unavailable—and it underscores Plaintiffs' failure to prove that ABDC engaged in unreasonable conduct.

During its opening statement, ABDC pointed to DEA's own description of its approach toward guidance: "grey is good."[148] The evidence at trial has borne this out. For instance, as to what constitutes a suspicious order, the CSA and its implementing regulations contains just 19 words. Yet, Mr. Rannazzisi agreed that DEA never told distributors what those words meant or how they should be implemented—that is, DEA provided no guidance to distributors on, for example, how to identify a suspicious order (*i.e.*, what constitutes "unusual size," "deviating substantially from a normal pattern," or "unusual frequency") or whether distributors could use thresholds or multipliers to identify suspicious orders.[149] Nor, as Mr. Rannazzisi testified, would DEA tell distributors exactly what should be reported or how their suspicious order monitoring programs should operate.[150]

DEA often has outright refused to provide guidance, and the sparse guidance DEA has provided has been riddled with inconsistences.[151] Over the last two decades, registrants, especially distributors, repeatedly have asked DEA for guidance on what constitutes a suspicious order, and on suspicious order monitoring and reporting generally.[152] No such guidance was forthcoming.

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[148] AM-WV-00896 (Summary of August 2017 Industry Meeting with DEA).

[149] *See* AM-WV-00896; 6/8 Tr. at 183:22-2 (Rannazzisi); 6/9 Tr. at 198:16-202:7 (Rannazzisi).

[150] 6/9 Tr. at 172:8-20, 200:11-17 (Rannazzisi).

[151] *See, e.g.*, 6/9 Tr. at 41:17-43:19 (Rannazzisi) (DEA's Acting Administrator concluding that Mr. Rannazzisi's "Dear Registrant" letters were not manifesting intent to bind DEA).

[152] *See, e.g.*, 6/9 Tr. at 174:25-175:21 (Rannazzisi) (DEA rejecting to respond to letters from distributors in 2011 and 2013 in which distributors requested guidance on suspicious order monitoring, reporting, and due diligence); 5/17 Tr. at 90:16-93:16 (May) (DEA declined to meet with ABDC to discuss ABDC's Revised Order Monitoring Program).

For instance, in 2018, ABDC requested a meeting with DEA to discuss how ABDC's revised SOM could "better serve the diversion control objectives of the Drug Enforcement Administration ("DEA") and combat the opioid crisis."[153] DEA, however, declined to meet with ABDC.[154]

Distributors are not alone in noting the absence of DEA guidance. In 2015, the Government Accountability Office issued a report entitled "Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access."[155] That report made recommendations to help "strengthen DEA's communication with and guidance for registrants," and "preventing diversion while ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical needs," which included a recommendation to "[s]olicit input from distributors, or associations representing distributors, and develop additional guidance for distributors regarding their roles and responsibilities for suspicious orders monitoring and reporting."[156]

D. The Volume Of Pills Shipped To Cabell And Huntington Does Not Prove Unreasonable Conduct

All that is left then is Plaintiffs' free-floating theory that Defendants must have engaged in culpable conduct because of the volume of prescription opioids shipped to Cabell and Huntington—what Plaintiffs call a "flood of pills." Putting aside the point that no law or regulation requires distributors to monitor for or take any action based on state, regional, or local distribution volumes, this theory fails on the facts as well.

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[153] AM-WV-00640.

[154] 5/17 Tr. at 93:10-93:16 (May).

[155] DEF-WV-02181.

[156] DEF-WV-02181 at 51.

The uncontroverted evidence introduced through Plaintiffs' own witnesses established beyond doubt that (1) the supply of opioids is driven by demand and (2) prescribers, not distributors, drive demand.[157] That point was driven home by the testimony of Plaintiffs' experts showing that the pattern of distribution of opioid pills into Cabell and Huntington and the pattern of prescriptions written by licensed physicians is the same.[158] DEA authorized the increasing supply of prescription opioids nationwide when it set—and repeatedly increased—the relevant production quotas.[159] DEA did so because, as Mr. Rannazzisi testified, such increases were necessary to meet legitimate medical and scientific need.[160]

The evidence also is uncontroverted that distributors have no obligation to police prescribers and should not second-guess medical decisions made by licensed prescribers.[161] On top of that, DEA, which had all the information on the number of prescription opioids distributed to these jurisdictions, never told distributors that too many pills were being shipped to Cabell or Huntington.[162]

The volume of prescription opioid, therefore, does not establish wrongful conduct.[163]

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[157] *See e.g.*, 5/26 Tr. at 242:6–20 (Rafalski) ("no other way" for distribution to increase than for doctors to prescribe more opioids); 5/11 Tr. at 134:24–135:3 (McCann) (prescribing and distribution volumes are "two sides of the same coin"); 6/9 Tr. at 190:8–13 (Rannazzisi) (opioid crisis "started with prescriptions"). The change in the standard of care that led to an increase in prescribing of opioid medications is discussed in the separate Memorandum of Law in Support of Defendants Motion for Judgment On Partial Findings Regarding Proximate Causation.

[158] 6/15 Tr. at 206:17-25, 207:13-16 (Keller); *see also* 5/11 Tr. at 134:24–135:18 (McCann)

[159] 6/8 Tr. at 199:2-4 (Rannazzisi).

[160] 6/8 Tr. at 199:5-203:18 (Rannazzisi); 6/9 Tr. at 87:7-11 (Rannazzisi).

[161] 6/9 Tr. at 154:14-155:7 (Rannazzisi); *see also* 5/26 Tr. at 117:8-12 (Rafalski).

[162] 6/9 Tr. at 94:10-15 (Rannazzisi).

[163] Plaintiffs also did not prove wrongful conduct based on a marketing theory either. Their marketing expert, Dr. Jakki Mohr, testified only that distributors engaged in what she called "marketing"—and she conceded that "there's nothing improper" about such marketing activities. 6/11 Tr. at 95:23-96:2, 112:19-21, 124:7-10. She had no opinion on whether any distributor marketing was false or misleading or unlawful. 6/11 Tr. at 96:7-10, 97:3-5, 123:22-

E. There Is No Evidence Of Diversion Of Prescription Opioids Shipped By ABDC To Huntington Or Cabell County

Plaintiffs' liability theory is that Defendants caused a public nuisance by shipping to Cabell and Huntington too many prescription opioids, which, in turn, were improperly diverted. Here, too, there is an entire failure of proof. Just as Plaintiffs have failed to prove any wrongful conduct on the part of ABDC, they also have failed to prove diversion in Cabell and Huntington—let alone diversion attributable to ABDC's conduct.[164] And without proof of diversion, Plaintiffs have not proven that ABDC's conduct caused any harm in Cabell or Huntington.

II. Plaintiffs Have Not Proved Culpable Conduct: "Unlawful Violations Of State And Federal Law"

In their summary judgment briefing, Plaintiffs argued that "unlawful conduct is a separate culpability category and that alleged violations of state and federal laws relating to drug

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124:6. Nor did she have any opinion on causation—she had not analyzed the impact of distributors' marketing on opioid sales or analyzed whether distributors' alleged marketing had any impact on the distribution of prescription opioids in Cabell and Huntington. *See* 6/11 Tr. at 78:6-7; 97:8-13, 97:23-98:3, 135:9-12. In the end, Dr. Mohr simply opined that distributors engaged in marketing, but marketing is not a tort.

[164] To begin with, there is no evidence that any of the orders shipped by ABDC met the definition of a "suspicious order." And the testimony of Plaintiffs' own witnesses controvert even the assertion an order that meets the regulatory definition of "suspicious"—but that lacks any indicia of diversion—is likely to be diverted or cause harm. For instance, Mr. Rafalski agrees that the vast majority of orders meeting the definition of a "suspicious order" are not likely to be diverted. 5/26 Tr. at 214:12–16; Prevoznik Dep. Tr. at 1206:6–1209:7 (testifying that there can be "legitimate" reasons for placing orders meeting the regulatory definition of suspicious including "a new customer base, prescriber, a new doctor's office opened"). And as for evidence of actual diversion in Cabell and Huntington, the record is bare. Mr. Rafalski admitted that he has no opinion that "diversion occurred at the pharmacy level." 5/26 Tr. at 135:8–13 (Rafalski). For his part, Mr. Rannazzisi said he had no knowledge at all on shipments to, let alone diversion in, West Virginia. 6/9 Tr. at 14:6–17 (testifying that he could not identify "any orders in Huntington or Cabell County that [he] believed ... should have been blocked" and that he has "not reviewed any documents related to West Virginia."); 6/10 Tr. at 23:8–9 ("I have no knowledge of any distributions into those counties."). Finally, as explained in more detail in Defendants' Memorandum of Law in Support of Defendants' Motion for Judgment on Partial Findings Regarding Proximate Causation, ABDC's conduct is not the proximate cause of any diversion that might have occurred.

distribution are sufficient to ground such a claim." ECF 1294 at 6 n.2. This Court did not rule on this argument then, *id.*, and it does not need to resolve this issue now either. Even if Plaintiffs are correct that a public nuisance claim under West Virginia law can be premised on "unlawful conduct," that provides no refuge for Plaintiffs for two reasons—one factual and one legal.

As for the facts, Plaintiffs have not established a violation of the laws they invoke—the Controlled Substances Acts.[165] The testimony of Plaintiffs' expert, Mr. Rafalski, did not establish a violation of the CSA. Nor did Mr. Rannazzisi's testimony. While Mr. Rannazzisi expressed his general views about distributors' conduct, nothing in his testimony establishes a violation of CSA on the part of ABDC (or, for that matter, any Defendant). And while Plaintiffs pointed to the more than 14 year old ISO directed to ABDC's Orlando distribution center—one that did not ship to West Virginia—the ISO was simply allegations and those allegations were resolved through a settlement agreement that did not establish or admit liability and ABDC paid no fine. And Mr. Rannazzisi conceded that, after the April 2007 ISO, DEA never had any reason to initiate any investigation or enforcement action against ABDC during his tenure with DEA.

As for the law, violations of the federal CSA or West Virginia Controlled Substances Act (WVCSA) cannot provide the basis for a state law public nuisance claim. Indeed, the law forbids this. Looking to first federal law, Supreme Court precedent forbids imposition of tort liability based on violations of a statute like the CSA, for which Congress had not authorized private enforcement. Allowing Plaintiffs to enforce the CSA indirectly through a common law cause of action would contravene congressional intent. Congress did not confer a private right of action for violations of the CSA. *See Alexander v. Sandoval*, 532 U.S. 275, 286 (2001) ("Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress.").

[165] *See* 5/3 Tr. at 22:11-21 (Plaintiffs' opening argument).

Instead, Congress granted the exclusive authority to enforce the federal CSA to the United States Attorney General who, in turn, has delegated that enforcement authority to the DEA. *See* DEA, *Practitioner's Manual, An Informational Outline of the Controlled Substances Act* 4 (2006 ed). Courts recognize that "according to its plain terms, the CSA is a statute enforceable ***only*** by the [United States] Attorney General and, by delegation, the Department of Justice." *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290 (D. Colo. 2010) (emphasis added) (internal alterations omitted) (citing *Schneller v. Crozer Chester Med. Ctr.*, 387 F. App'x 289, 293 (3d Cir. 2010)). Nothing in the text or structure of the CSA suggests that Congress intended to confer legal rights—much less an enforceable private remedy—on the states or their counties and cities. *See id.* at 1290; *McCallister v. Purdue Pharma L.P.*, 164 F. Supp. 2d 783, 793 n.16 (S.D.W. Va. 2001) (finding no such "legislative intent"). Consequently, "federal courts [including in the opioid litigation] have uniformly held that the CSA does not create a private right of action." *Smith*, 164 F. Supp. 3d at 1290; *see also West Virginia v. McKesson Corp.*, Case No. 2:17-03555, Dkt. 21 at 14-15 (S.D.W. Va. Feb. 15, 2018); *Floyd v. Feygin*, No. 507458/17, 2018 WL 6528728, at *6 (N.Y. Sup. Ct. Dec. 6, 2018) (holding that state-law negligence claim was "preempted" by CSA and DEA regulations).

And, where, as here, Congress has not conferred a private right of action and instead has delegated the authority to enforce a statute exclusively to the United States Attorney General, no one else can enforce the statute indirectly through state common law cause of action based on violations of the statute.[166] *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 118 (2011) (holding that a private party could not indirectly enforce Section 340B of Public Health Services Act, which

[166] This bar on indirect enforcement holds even if private lawsuits might encourage compliance with a federal statute. *See Alexander*, 532 U.S. at 286–87; *Astra*, 563 U.S. at 121.

contains no private right of action, through state law breach of contract claim); *Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994) (noting that permitting a plaintiff to enforce statutory or regulatory duties through a common law claim "would, in effect, be permitting a private cause of action" under the statute).[167]

Allowing Plaintiffs to prove a public nuisance claims based on alleged violations of the CSA would authorize private enforcement of the statute—an impermissible end-run around the limits set by Congress on who may enforce the statute that would render meaningless the absence of a private right of action. *See Astra*, 563 U.S. at 118 ("The absence of a private right [of action] to enforce the statutory ... obligations would be rendered meaningless if [plaintiffs] could overcome that obstacle by suing to enforce the contract's ... obligations instead."); *Myers*, 17 F.3d at 901 (permitting a plaintiff to enforce statutory or regulatory duties through common law negligence "would, in effect, be permitting a private cause of action" under the statute).

The same is true when it comes to the WVCSA. Like the CSA on which it is modeled, the WVCSA does not contain a private right of action. Instead, the statute vests the authority to "administer [its] provisions" exclusively in the West Virginia Board of Pharmacy and establishes a specific enforcement scheme, providing that "[c]omplaints arising under any provision" of WVCSA article "***shall*** be handled" pursuant to procedures set forth in the statute. W. Va. Code § 60A-2-201(a); *id.* § 60A-8, 10. Nor is there an implied private right of action to enforce the

[167] *See, e.g.*, *Coffman v. Bank of Am., NA*, No. 2:09-cv-00587, 2010 WL 3069905, at *8 (S.D. W. Va. Aug. 4, 2010) ("Plaintiff may not circumvent the [Office of Thrift Supervision]'s exclusive authority to implement disclosure requirements for federal savings banks through a state law claim of unconscionable inducement."); *Durr v. Strickland*, 602 F.3d 788, 789 (6th Cir. 2010) (affirming dismissal of declaratory judgment action lawsuit filed by Ohio inmate facing execution arguing that state's means of execution violate[d] the Federal Controlled Substances Act, the Federal Food, Drug and Cosmetic Act, and various federal regulations associated with these Acts because no private cause of action exists under either act).

WVCSA. To establish an implied private right of action, a plaintiff must satisfy the four-part test promulgated in *Hurley v. Allied Chemical Corp,* 262 S.E.2d 757 (1980). There is none here: (1) Plaintiffs are not "member[s] of the class for whose benefit the statute was enacted"; [168] (2) the legislature did not "intend[]" to create a private right of action;[169] (3) Plaintiffs' cause of action is not "consistent with the underlying purposes of the legislative scheme"[170] and (4) Plaintiffs cause of action would intrude into an area delegated exclusively to the State. *See id.* at 763.

CONCLUSION

Plaintiffs Cabell County and the City of Huntington have now put on their case. At the end of seven weeks of trial, with more than 30 witnesses and hundreds of exhibits, the result is clear: there is no evidence even suggesting that ABDC acted unreasonably. After a full airing of a plaintiff's case, if it becomes apparent that the case is unfounded, judgment for the defendant is warranted. So it is here and ABDC's motion should be granted.

Respectfully Submitted,

AmerisourceBergen Drug Corporation

/s/ Gretchen M. Callas
Gretchen M. Callas (WVSB #7136)
JACKSON KELLY PLLC

[168] *See* Opinion and Order, *In Re: National Prescription Opiate Litig.*, N.D. Ohio, No. 1:18-op-45749 (June 13, 2019), Dkt. 67 at 24 (J. Polster) (expressly holding that Plaintiffs Blackfeet Tribe and Muscogee Nation could not base their negligence per se claims on the CSA because they were "not the intended beneficiaries of the CSA."); *accord In Re: Nat'l Prescription Opiate Litig.*, N.D. Ohio No. 1:17-MDL-2804, at 52-53 (Feb. 21, 2020), ECF No. 3177 (dismissing negligence *per se* claims of another plaintiff on the same grounds). Nothing in the WVCSA suggests otherwise.

[169] W. Va. Code § 60A-2-201(a).

[170] *See, e.g., Gen. Pipeline Constr., Inc. v. Hairston*, 765 S.E.2d 163, 172 (2014) ("Because of the Legislature's specificity in creating the cause of action in an agency of the State of West Virginia, we cannot say the Legislature intended also to infer the creation of a private cause of action in the plaintiffs.").

Post Office Box 553
Charleston, WV 25322
Telephone: (304) 340-1000
Facsimile: (304) 340-1050
gcallas@jacksonkelly.com

/s/ *Robert A. Nicholas*
Robert A. Nicholas
Shannon E. McClure
Joseph J. Mahady
REED SMITH LLP
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
Tel: (215) 851-8100
Fax: (215) 851-1420
rnicholas@reedsmith.com
smcclure@reedsmith.com
jmahady@reedsmith.com

CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2021, the forgoing ***AmerisourceBergen Drug Corporation's Memorandum in Support of Motion for Judgment Under Rule 52(c) Based On Plaintiffs' Failure To Prove Culpable Conduct*** was sent to Counsel for the Plaintiffs and Defendants using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Gretchen M. Callas
Gretchen M. Callas (WVSB # 7136)